K070814

CONFIDENTIAL

MAY 30 2007

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.98.

Sponsor:	Confluent Surgical, Inc. 101A First Avenue Waltham, MA 02451
Contact:	Kristine Burke Phone: (781) 839-1738 Fax: (781) 839-1763 E-mail: Kristine.Burke@tycohealthcare.com
Device Trade/Proprietary Name(s)	Confluent Surgical MicroMyst Applicator Confluent Surgical Air Pump
Classification Name:	Piston Syringe (21 CFR 880.5860) Class II Product Code: FMF
Common Name:	Confluent Surgical MicroMyst Applicator and Confluent Surgical Air Pump
Predicate Device(s):	Confluent Surgical MicroMyst Applicator and Air Pump (K050998)

DEVICE DESCRIPTION

Product Description:	The Confluent Surgical MicroMyst Applicator will be configured using the following components: • Applicator • Air line with Filter • Air Source
Indications for Use:	The Confluent Surgical MicroMyst Applicator and Air Pump are indicated for use in the simultaneous delivery of two non-homogenous fluids or solutions onto a surgical site.
Technological Characteristics:	The proposed device incorporating the modification discussed in this submission has similar technological characteristics compared to the predicate device

Safety and Performance:	Testing conducted to characterize performance of the proposed device incorporating the modification discussed in this submission has demonstrated that it is substantially equivalent to the predicate device and that it is suitable for the intended use specified.
Conclusion:	Based on (1) safety and performance data, and (2) similarities in indication for use, operating principle, design, materials, and manufacturing processes, the Confluent Surgical MicroMyst Applicator has been shown to be substantially equivalent to a predicate device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2007

Ms. Kristine Burke
Regulatory Affairs Manager
Confluent Surgical, Incorporated
101A First Avenue
Waltham, Massachusetts 02451

Re: K070814
Trade/Device Name: Confluent Surgical MicroMyst™ Applicator and Air Pump
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 09, 2007
Received: May 10, 2007

Dear Ms. Burke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

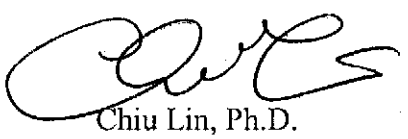
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070814

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Confluent Surgical MicroMyst™Applicator and Air Pump

Indications for Use: The Confluent Surgical MicroMyst Applicator and Air Pump are indicated for use in the simultaneous delivery of two non-homogenous fluids or solutions onto a surgical site.

Prescription Use ✓ AND/OR Over-the -Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] Sign-Off)
[illegible]sion of Anesthesiology, General Hospital,
[illegible]ection Control, Dental Devices

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